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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,846	11/11/2005	Jacques Beaurain	LDR/10/US - 21249.014US1	7881
36485	7590	12/26/2007	EXAMINER	
J. SCOTT DENKO			YANG, ANDREW	
ANDREWS & KURTH LLP				
111 CONGRESS AVE., SUITE 1700			ART UNIT	
AUSTIN, TX 78701			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,846

Applicant(s)

BEAURAIN ET AL.

Examiner

Andrew Yang

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/15/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicants' amendment filed on October 16, 2007.

Claim Objections

It is noted that claims 26 and 31-35 are still in improper multiple dependent form since they still depend on claim 24 which is also a multiple dependent claim. In light of applicants remarks/arguments they will be considered for examination since the previously filed preliminary amendment included the proper corrections. Proper correction to the most recent listing of claims is still required.

For the purposes of examination, claim 26 is considered dependent from claims 22 or 23 and claims 31, 33-35 are considered to be dependent from claims 22 or 23.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 35 claims that the male means is a rib located at the center of the prosthesis; however Claim 1 claims that the cooperation means are not located in the

middle of the core. From the figures it also appears that the core is centered on the plates and thus the center of the prosthesis will coincide with the middle of the core. It is unclear how the rib can be located at the center of the prosthesis and not in the middle of the core.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 58 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 depends from claim 0, which is not a listed claim. It is noted that in the preliminary amendment filed, claim 58 depends from claim 57 and will be considered as such for the purposes of examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

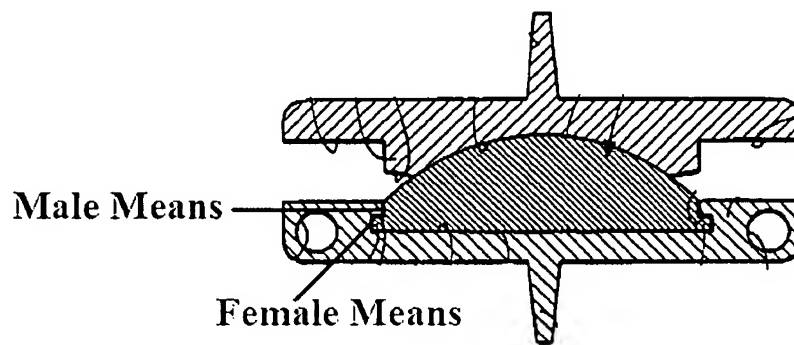
Claims 21, 27, 28, 36, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (U.S. Patent No. 6368350).

Erickson et al. discloses an intervertebral disc prosthesis 10 with upper plate 20, a lower plate 21, and a core 22. The core 22 has an upper surface 46 that is in contact with a lower surface 25 of the upper plate 20 and a lower surface 47 of the core 22 is in contact with an upper surface 28 of the lower plate 21. The upper plate 20 is moveable with respect to the core 22 and the core 22 is moveable in translation and rotation with respect to the lower plate 21 (Column 7, Lines 30-35). There are cooperation means not located in the middle of the core between the lower plate and the core to limit translation movements of the core with respect to the lower plate around an axis parallel to the lower plate 21 and means to limit rotational movements of the core with respect to the lower plate around an axis perpendicular to the lower plate 21 (Column 7, Lines 65-67). The core can be made of polyethylene (Column 5, Lines 58-60). Furthermore, the lower surface 25 of the upper plate 20 is concave and complimentary to the upper surface 46 of the core 22 (Column 7, Lines 14-21). Furthermore, the intervertebral disc prosthesis can have one circular opening 410 along its front side (Figure 33) to receive an anchoring means in the form of screws (Column 9, Lines 60-64) and are considered nail shaped.

Claims 21-23, 30, 34, 41, 42, 46-49, 52, 56, 57, 61, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Marnay et al. (U.S. Patent No. 6936071).

Marnay et al. discloses an intervertebral implant with an upper plate 2, a lower plate 3, and a core 4. Core is made of polyethylene (Column 5, Line 37), has an upper

convex surface 25 in contact with the lower concave surface 12 of the upper plate 2 and a lower surface in contact with the upper surface of the lower plate 3, with the upper plate 2 being moveable with respect to the core 4 (Column 5, Lines 43-53). The lower plate has cooperation means 27 not located in the middle of the core between the lower plate and the core. The cooperation means serves to fix the core 4 to the lower plate 3 (Column 5, Lines 16-19), thus limiting translation movements with respect to the lower plate around an axis parallel to the lower plate, and rotation movements with respect to the lower plate around an axis perpendicular to the lower plate. With reference to the figure on the next page, the cooperation means has a male means and a female means. The male means cooperates with a female means of the core 4, and the female means of the lower plate cooperates with a male means of core 4. In both cases the cooperating means of the lower plate 3 have substantially the same dimensions of the cooperating means of the core 4.



The cooperation means, is also comprised of a stop, with a male portion and a female portion located along an edge of the prosthesis as seen in the figure above. Furthermore, the core 4 is considered translatable with the lower plate since it is slide into place along an axis parallel to the lower plate, and can be rotated about an axis

perpendicular to the lower plate prior to full insertion of the core. The female portion is disposed on the lower plate and the male portion 26 is disposed on the core. But it can also be seen that the core has a female portion that cooperates with the male means on the lower plate. The female portion can be considered a recess and groove above element 26 and the male portion is part of a wall.

Claims 21, 22, 29, 33, 41, 47, 50, 56, 62, and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Pisharodi (U.S. Patent No. 6610093).

Pisharodi discloses an intervertebral disc prosthesis 10G having an upper plate, a lower plate, and a core 26G. An upper surface of the core is in contact with a lower surface of the upper plate and a lower surface of the core is in contact with an upper surface of the lower plate (Figure 6). The upper plate is moveable with respect to the core and the core is moveable in translation and rotation with respect to the lower plate (Column 5, Lines 14-24). There are cooperation means 94G no located in the middle of the core so as to limit translation movements around an axis parallel to the lower plate and to limit rotation movements of the core with respect of an axis perpendicular to the plate (Column 5, Lines 20-24). The lower plate has the male means 94G cooperating with the female means 90G of the core (Figure 6). The dimensions of the male means are less than those of the female means (Column 5, Lines 20-24).

With regard to claim 33, elements 94G can also be considered male means that are located near the center of the lower plate since they are near the center line of the lower plate (Figure 6) and the female means 90G can be considered wells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (U.S. Patent No. 6368350) in view of Graf (U.S. Patent No. 6419706).

Erickson et al. discloses the claimed invention and also further discloses the used of a second core that has a thickness that differs from the thickness of the first core (Column 9, Lines 39-40). Erickson et al. fails to disclose the core forming an acute angle in a front-rear direction. Graf teaches an intervertebral disc with a core 4 and upper and lower plates 6. The core 4 has a greater transverse dimension at its front part than at its rear, forming an acute angle from front-rear direction, which gives the device a lordosis appearance, which is found to be advantageous from a physiological point of view (Column 9, Lines 57-59). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Erickson et al. with a core that forms an acute angle in the front-rear direction in view of Graf so that the device would have a lordosis appearance that is physiologically advantageous.

With regard to claim 26, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Erickson et al. as modified by Graf with the angle between the upper and lower plates to be between 0 and 15 degrees, since it has been held that where the general conditions of a claim are

disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (U.S. Patent No. 6368350) in view of Pisharodi (U.S. Patent No. 6610093).

Erickson et al. discloses the claimed invention except for the upper plate is convex on its upper surface. Pisharodi teaches an intervertebral implant with an upper section with a top surface being convex shaped in order to account for the anatomy of the vertebral end plates (Column 2, Lines 4-6). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Erickson et al. with the upper plate having a convex upper surface in view of Pisharodi in order to account for the anatomy of the vertebral end plates.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (U.S. Patent No. 6368350).

Erickson et al. discloses the claimed invention except for the openings being rectangular. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the holes of Erickson et al. with a rectangular shape, since applicant has not disclosed that such solves any stated problem or is anything more than one of numerous shapes or configurations a person with ordinary skill in the art would find obvious for the purpose of providing an anchoring means into adjacent vertebrae. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 43-45 and 58-60 rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay et al. in view of Pisharodi (U.S. Patent No. 6610093).

Marnay et al. discloses the claimed invention as well as anchors 6 on opposite sides of the prosthesis configured to engage adjacent vertebrae. Marnay et al. fails to disclose the upper plate is convex on its upper surface. Pisharodi teaches an intervertebral implant with an upper section with a top surface being convex shaped in order to account for the anatomy of the vertebral end plates (Column 2, Lines 4-6). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Marnay et al. with the upper plate having a convex upper surface in view of Pisharodi in order to account for the anatomy of the vertebral end plates.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay et al. (U.S. Patent No. 6936071) in view of Graf (U.S. Patent No. 6419706).

Marnay et al. discloses the claimed invention except for the core forming an acute angle in a front-rear direction. Graf teaches an intervertebral disc with a core 4 and upper and lower plates 6. The core 4 has a greater transverse dimension at its front part than at its rear, forming an acute angle from front-rear direction, which gives the device a lordosis appearance, which is found to be advantageous from a physiological point of view (Column 9, Lines 57-59). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Marnay et al. with a core that forms an acute angle in the front-rear direction in view of Graf so that the device would have a lordosis appearance that is physiologically advantageous.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay et al. (U.S. Patent No. 6936071) in view of Coates et al. (U.S. Patent No. 6899735).

Marnay et al. discloses the claimed invention except for a second core with a thickness that differs from the first core. Coates et al. teaches an intervertebral disc with a core 70 and upper and lower plates 20. After installation, the core 70 between the plates 20 can be removed to allow the surgeon to try another size of the core 70 without removing the plates from the vertebral members (Column 1, Lines 66-67 and Column 2 Lines 1-3). This feature is provided with the device since it is not always possible to predetermine the size of the core needed for the operation (Column 1, Lines 34-40). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Marnay et al. with a second core with a thickness different from the first core in view of Coates et al. to allow a surgeon to try a different size core since it is not always possible to predetermine the proper size core for an operation.

Claims 31, 32, 51 and 53 rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (U.S. Patent No. 6610093).

Pisharodi discloses the claimed invention except for the pins to be curved and the female means to be corresponding recesses and the male portion to be a tae fixed by a dowel. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the male means of the lower plate with curved pins towards the inside of the prosthesis to engage a recess or a tagged fixed by a dowel, since applicant has not disclosed that such solve any stated problem

or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a means for limiting motion. In re Dailey and Eilers, 149 USPQ 47 (1966).

Response to Arguments

In response to Applicant's argument that Marnay et al. fails to disclose the core to be configured for or moveable in rotation and translational movements with respect to the lower end plate, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). It is considered that since the core of Marnay et al. is a separate piece from the lower endplate and can translate along the lower endplate as well as rotate with respect to the lower endplate when the core is not fully inserted.

Applicant's arguments with respect to claims not previously rejected by Marnay et al. have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached on 8:00am-5:30pm: Monday-Friday.

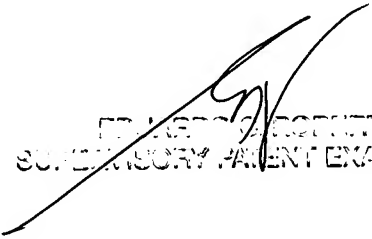
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AY
12/18/2007


SUPERVISORY PATENT EXAMINER